

REMARKS

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

Amendments to the title, specification and abstract are editorial in nature and have been made to correct errors in spelling, grammar, and punctuation; to provide consistency in terminology throughout the entire application; and to otherwise eliminate informalities existing in the original description. No new matter has been added. Paragraph numbers have been added to the "substitute" specification, but are not indicated on the marked-up copy.

A parts list is now being submitted.

FIGS. 15 and 16 are being deleted.

Amendments to the claims are editorial in nature, and no new matter has been added. Where applicable, subparagraphs in the claims have now been identified with lower case letters.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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Attachments: Substitute specification and abstract
 Marked-up copy of original specification
 and abstract
 New Parts List

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Attorney Docket No. 2856.06US02

**PROTECTIVE SYSTEM OR APPARATUS INCLUDING
GUIDEWIRE HAVING DEPLOYABLE
SHEATHLESS ~~PROTECTIVE~~ FILTER
AND METHOD UTILIZING SAME**

RELATED APPLICATION

5 This application claims the benefit of U.S. Provisional Application No. 60/437,166, filed December 30, 2002, incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of vascular medical devices. More 10 specifically, the present invention relates to a ~~guidewire~~ protective system for use in vascular *or apparatus*
includes procedures that ~~produces~~ a deployable ~~converg~~ filter *that is sheathless* ~~without the use of a sheath~~.

BACKGROUND OF THE INVENTION

Arterial disease involves damage that happens to the arteries in the body. Diseased 15 *arteries* ~~vessels~~ can become plugged with thrombus, plaque, or grumous material that may ultimately lead to a condition known as ischemia. Ischemia refers to a substantial reduction or loss of blood flow to the heart muscle or any other tissue that is being supplied by the artery and can lead to permanent damage of the affected region. While arterial disease is most commonly associated with the formation of hard plaque and coronary artery disease in the heart, similar damage can 20 happen to many other vessels in the body, such as the peripheral vessels and cerebral vessels, due to the *build up* of hard plaque or softer thrombus or grumous material within the lumen of an artery or vein.

A variety of vascular medical devices and procedures have been developed to treat diseased vessels. The current standard procedures include bypass surgery (where a new blood vessel is grafted around [the] ^a narrowed or blocked artery) and several different types of non-surgical interventional vascular medical procedures, including ^a angioplasty (where a balloon on a catheter is inflated inside [the] ^a narrowed or blocked portion of [the] ^{an} artery in an attempt to push back [the] plaque or thrombotic material), stenting (where a metal mesh tube is expanded against [the] ^a narrowed or blocked portion of [the] ^{an} artery to hold back [the] plaque or thrombotic material), and debulking techniques in the form of atherectomy (where some type of high speed or high power mechanism is used to dislodge [the] hardened plaque) or thrombectomy (where some type of ^{or} mechanism or infused fluid is used to dislodge grumous ^{or} thrombotic material). In each of these ^{interventional} vascular medical procedures, a very flexible guidewire is routed through the patient's vascular system to a desired treatment location and then a catheter that includes a device on the distal end ^y appropriate for the given procedure ^y is tracked along the guidewire to the treatment location.

Although interventional vascular procedures avoid many of the complications involved in surgery, there is a possibility of complications if some of the plaque, thrombus or other material ^{or other vessel} breaks free and flows downstream in the artery, potentially causing a stroke, a myocardial infarction (heart attack) ^y or other tissue death. One solution to this potential complication is to use some kind of occlusive device or filtering device to block or screen the blood flowing downstream of the treatment location.

20 The use of a protective device in the form of an occlusive device or filtering device as part of a vascular procedure is becoming more common in debulking procedures performed on heart bypass vessels. Most heart bypass vessels are harvested and transplanted from the

saphenous vein located along the inside of the patient's leg. The saphenous vein is a long, straight vein that has a capacity more than adequate to support the blood flow needs of the heart. Once transplanted, the saphenous vein is subject to ~~arterial disease caused by~~ plaque or thrombotic materials ~~that build up~~ in the grafted arterial lumen. Unfortunately, the standard 5 interventional vascular treatments for debulking are only moderately successful when employed to treat saphenous vein coronary bypass grafts. The complication rate for a standard balloon angioplasty procedure in a saphenous vein coronary bypass graft is higher than in a native vessel with the complications including embolization, "no-reflow" phenomena, and procedural related myocardial infarction. Atherectomy methods including directional, rotational, and laser devices 10 are also associated with a high degree of embolization resulting in a greater likelihood of infarction. The use of stents for saphenous vein coronary bypass grafts has produced mixed results. Stents provide for less restenosis, but they do not eliminate the risk of embolization and infarction. *incurred by standard balloon angioplasty*

In order to overcome the shortcomings of these standard non-surgical interventional 15 treatments in treating saphenous vein coronary bypass graft occlusion, embolic protection methods utilizing a protective device distal to the lesion have been developed. The protective device is typically a filter or a balloon. Use of a protective device in conjunction with an atherectomy or thrombectomy device is intended to prevent emboli from migrating beyond the 20 protective device and *to* allow the embolic particles to be removed, thereby subsequently reducing the risk of myocardial infarction. When the protective device is a balloon, the balloon is inserted and inflated at a point distal to the treatment site or lesion site. Therapy is then performed at the ~~treatment~~ site and the balloon acts to block all blood flow, which prevents emboli from traveling

beyond the balloon. Following treatment, some form of particle removal device must be used to remove the dislodged emboli prior to balloon deflation. U.S. Patent No. 5,843,022 uses a balloon to occlude the vessel distal to a lesion or blockage site. The occlusion is treated with a high pressure water jet, and the fluid and entrained emboli are subsequently removed via an extraction tube. U.S. Patent No. 6,135,991 describes the use of a balloon to occlude the vessel allowing blood flow and pressure to prevent the migration of emboli proximally from the treatment device. While effective as a protective device, balloons may result in damaged tissue due to lack of blood flow downstream of the treatment area due to the time required to inflate and deflate the balloon.

10 To overcome this disadvantage, most development in relation to occlusive devices has focused on devices that screen the blood through a filter arrangement. An early arterial filtering system utilizing a balloon catheter with a strainer device is described in U.S. Patent No. 4,873,978. The device is inserted into a vessel downstream of the treatment site. The strainer responds to actuation of a separately introduced control cable to open and close a plurality of 15 tines capable of retaining dislodged particles. After treatment, the strainer is collapsed and the entrapped emboli are removed from the body. The additional wire, however, creates additional complexity for the user.

More recently, filter designs have been deployed through the use of a single guidewire in which the filter device is transported to the deployment area within a sheath or catheter. Typical 20 filters have either an umbrella shape to capture emboli or a tube shape in which the proximal end contains larger openings than the distal end so as to allow the blood and debris to enter the filter. The filter thus presents an operational face to the flow of blood within the vessel as provided by

the distal end of the tubular filter that is concave in orientation. Particles are captured within the concave face of the filter and are then retracted out of the vessel when the entire device is removed from the body.

a filter

One of the challenges regarding filters is the manner in which ~~it~~ is transported to and 5 from the area of interest. U.S. Patents Nos. 6,042,598, 6,361,546, 6,371,970, 6,371,971 and 6,383,206 describe various examples of filter arrangements that are to be deployed through a sheath, while U.S. Patents Nos. 6,080,170, 6,171,328, 6,203,561, 6,364,895, and 6,325,815 describe filters that are deployed ~~by~~ ^a catheter. For example, U.S. Patent No. 6,371,971 describes a blood filter positioned by way of a single guidewire, covered by a sheath for advancement 10 ~~a vessel~~ through ~~the channel~~ ^{a vessel}. The sheath compresses ~~the~~ struts of the filter while in transit. An interventional procedure requires deployment of the sheath along a guidewire down ^{the} stream of the vascular occlusion. The sheath is retracted and the filter expands to a predetermined size. The filter is retrieved after the procedure by deploying the sheath back down the guidewire, capturing the filter and removing the system from the patient.

15 The disadvantage associated with this type of filter is the added thickness of the device due to the use of a sheath to deploy the filter. Typical sheath diameters exceed 0.040 inches. Insertion of the sheath can damage the vessel during routing and deployment to the occluded area and during removal. Moreover, the bulky sheath protecting the filter can hamper the debris removal or cause further embolization.

20 There is a need then for a protective device capable of embolization protection for vascular and arterial procedures without the design limitations of the existing approaches. ^{thus} Occlusive balloons can remain in place too long ^{thus} increasing the risk of vessel damage

downstream of the occlusion. Protective filters avoid this problem but suffer from complicated deployment and retraction schemes. Moreover, existing filters are limited in range due to the filter framework, which also may result in vessel damage. It would be desirable to provide an occlusive filter device ^{that is along a single guidewire} easily deployable without a large diameter sheath ^{along a single} ~~guidewire~~ and ~~guidewire~~ that reduces the potential for vessel damage.

SUMMARY OF THE INVENTION

or apparatus

The present invention is a ~~guidewire~~ protective system for use in vascular procedures comprising a tubular guidewire, a control cable disposed within the lumen of ~~a~~ guidewire; and a

10 sheathless ~~convex protective~~ filter distally coupled to the control cable and proximally coupled to ~~tubular~~ ~~sheathless~~ ~~sheathless~~ the guidewire. The filter radially expands as the distal end of the filter is drawn toward the ~~of the sheathless filter~~ proximal end in response to displacement of the control cable relative to the tubular guidewire.

The primary filter action is provided by the outer convex surface of the filter, which is the first ~~to come~~ ~~a blood~~ ~~sheathless~~ surface in contact with the flow of blood within ~~the~~ vessel.

15 In a preferred embodiment, the filter is comprised of a braided Nitinol wire ~~skeleton~~ ~~framework~~ ~~woven strands~~ ~~applied~~ ⁷ frame in the form of a tube to which ~~other fibers~~ are ~~woven~~ to create a filter mesh. In one embodiment, the ~~other fibers~~ are multifilament polymer fibers. In an alternate embodiment, the ~~woven strands~~ ^{The distal end of the} ~~other fibers~~ are ~~other~~ Nitinol wires of different diameters. ~~A~~ control cable is attached to the ~~sheathless~~ and the distal end of the ~~tubular mesh~~ filter. The proximal end of the control cable extends beyond the

20 proximal end of the tubular guidewire for access. Pulling the proximal end of the control cable ~~sheathless~~ ~~of the sheathless filter~~ draws the distal end of the ~~tubular mesh~~ filter towards the proximal end, which is attached to the ~~tubular~~ ~~sheathless~~ ~~blood~~ guidewire. The filter expands radially until it either fills the vessel or reaches a maximum

~~mesh~~
expansion point at which filter openings are still smaller than the smallest expected particle size
~~sheathless~~
of clinical significance. The filter may be locked in place to prevent premature closure of the
~~sheathless~~
filter. In one embodiment, the filter is provided with a radiopaque marker that provides an
~~sheathless~~ indication of the position and deployment state of the filter ~~under fluoroscopy~~

5 Unlike existing filters that have a concave operational surface, the proximal ~~face~~ of the
~~sheathless~~ deployed filter of the present invention has a convex shape that provides a ~~first~~ filter surface.
~~filter~~

10 Particle removal from the convex ~~surface~~ is preferably accomplished in conjunction with a catheter-based aspiration device, such as a ~~Thrombectomy~~ device, U.S. Patent No. 5,370,609, commonly referred to as an AngioJet®. The use of an aspiration device enables removal of the majority of particles trapped by the convex ~~face~~ prior to retraction of the filter through an evacuation lumen. Should debris escape the mesh of the convex ~~front~~ surface, the interior distal ~~surface~~ ~~sheathless~~ ~~secondary~~ ~~face~~ of the filter creates a ~~second~~ concave ~~back~~ filter surface which also traps debris. Extraction requires reducing the filter diameter by retracting the ~~distal~~ control cable. The collapsed ~~sheathless~~ ~~tubular~~ filter holds debris trapped by the secondary filter surface during the removal process.

15 In a preferred embodiment, the tubular guidewire is advanced over the control cable in a ~~intermediate~~ ~~tubular~~ ~~guidewire~~ ~~sheathless~~ ~~to~~ ~~tubular~~ ~~surface~~ ~~by a clamp~~ ~~created by a projection on~~ ~~surface~~ ~~sheathless~~ ~~radial~~ ~~expansion~~ ~~of the~~ filter is limited to maintain appropriate maximum allowable mesh

spacing. A stop is crimped on to the control cable beyond the distal end of the tubular guidewire.

stop

retraction

The ~~crimp~~ blocks control cable ~~advancement~~ into the tubular guidewire at the acceptable limit of

sheathless

deployment. Alternatively, the location at which the proximal end of the filter is joined to the tubular guidewire can be used to control the extent of deployment.

5 In one embodiment for coronary vascular procedures, the tubular guidewire ~~assembly~~

180 outer tubular guidewire

preferably has an effective length of ~~190~~ cm. The diameter of the ~~shaft~~ would be 0.014 inches.

sheathless

Starting profile of the filter is 0.030 inches and fully expanded profile would be 0.3 inches.

There is no deployment delay as with inflating a balloon. Deployment is immediate upon activation of the control cable. This embodiment in combination with an aspiration debris

10 removal device is particularly adapted to provide distal embolization protection in debulking vascular interventional procedures, such as those involving a blocked saphenous vein coronary

bypass graft. The aspiration debris removal device removes the majority of particles while the

sheathless

filter captures the remainder. Alternatively, the present invention may be configured and sized

neurovascular

for use in peripheral vascular procedures or ~~neurovascular~~ procedures.

or apparatus

15 The advantage of the ~~guidewire~~ protective system of the present invention is that ~~the~~

~~protective device~~ behaves like an ordinary guidewire yet does not require a bulky sheath for

sheathless filter of the

deployment or retrieval. Unlike balloon occlusive devices that block a vessel, the present

invention ~~serves as a filter that~~ allows for the continuous flow of blood, thus decreasing potential

downstream

sheathless filter of the

damage to ~~downstage~~ tissue. Unlike other filters, the present invention has a variable diameter

20 based on the extent of deployment, which further results in a range of filtration capabilities.

Moreover, the flexible nature of the filter mesh conforms to vessel shape and the "soft"

multifilament polymer fibers create less damage. There are no complicated mechanical arrangements or valve systems internal or external to the ~~guidewire~~ protective system ^{or apparatus}

BRIEF DESCRIPTION OF THE DRAWINGS

5 FIG. 1 is a ~~perspective~~ view of the ~~present invention~~ prior to expansion of the filter ^{side protective system or apparatus sheathless}

~~Assembly~~

FIG. 2 is a ~~perspective~~ view of the ~~present invention~~ after expansion of the filter ^{side protective system or apparatus sheathless}

~~Assembly~~

10 FIG. 3 is a close-up ~~perspective~~ view of the filter ~~assembly~~ of the ~~present invention~~ prior to expansion. ^{hypoth} ^{side protective system or apparatus featuring the sheathless}

to expansion.

15 FIG. 4 is a close-up ~~perspective~~ view of the filter ~~assembly~~ of the ~~present invention~~ ^{hypoth} ^{side protective system or apparatus featuring the sheathless}

partially expanded.

20 FIG. 5 is a close-up ~~perspective~~ view of the filter ~~assembly~~ of the ~~present invention~~ at full operational expansion. ^{hypoth} ^{side protective system or apparatus featuring the sheathless}

25 FIG. 6 is a close-up ~~perspective~~ view of the wire ~~mesh~~ framework of the filter ~~assembly~~ of the ~~present invention~~. ^{detail} ^{braided} ^{and filter mesh} ^{sheathless}

30 FIG. 7 is a ~~perspective~~ view of the ~~present invention~~ with a clamp attached. ^{side protective system or apparatus} ^{to the control cable}

35 FIG. 8 is a side view of another embodiment of the ~~present invention~~ ^{protective system or apparatus}

20 shown in FIG. 8.

40 FIG. 10 is a detailed ~~cross-sectional~~ view of the ~~distal~~ tip of the embodiment shown in FIG. 8. ^{side} ^{flexible guidewire tip}

magnified

filter

sheathless

FIG. 11 is a detailed view of a section of the mesh of one embodiment of the protective filter.

filter.

sheathless

FIG. 12 is a detailed view of the proximal attachment of the protective filter to the tubular guidewire.

5 FIGs. 13 and 14 are cross-sectional views of pieces of a clamp arrangement for use with one embodiment of the present invention.]

FIGs. 13 and 14

fit used

FIGs. 15 and 16 are cross sectional views of an interference feature for use with one embodiment of the present invention.

10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT~~S~~

or apparatus

The present invention is a ~~guidewire~~ protective system for use in vascular procedures.

~~protective system or apparatus~~
The ~~invention~~ includes a tubular guidewire having a proximal end, a distal end, and a lumen ~~;~~ ; a control cable, having a proximal end and a distal end, ~~is~~ disposed in the lumen of the tubular guidewire ~~;~~ and ~~;~~

15 → A sheathless ~~protective~~ filter distally coupled to the control cable and proximally coupled ~~to the tubular~~ ~~sheathless proximal exterior primary filter~~

~~filter~~ to the tubular guidewire ~~expands in response to the displacement of the control cable relative to the guidewire such that the filter presents at least a convex surface to the flow of blood in a blood vessel.~~ In one embodiment, the sheathless ~~protective~~ filter has a distal interior ~~face~~ which provides a secondary ~~filtering~~ surface. ~~The distal interior face presents a concave surface to the blood~~

20 flow of blood within a vessel.

~~protective system or means~~
The ~~guidewire protection~~ apparatus is preferably provided with a mechanism for resisting

displacement of the control cable relative to the tubular guidewire. In one embodiment, ~~an~~

a short tube intermediate the

5 ~~intermediate shaft~~ is disposed between the tubular guidewire and control cable at the proximal end of the tubular guidewire. The ~~intermediate shaft~~ is crimped to resist movement of the control cable. When the control cable is adjusted, it thus remains in place due to the resistance created by the ~~intermediate shaft~~ short tube. In another embodiment, the control cable contains a stop so as to limit displacement. In a further embodiment, a clamping mechanism is used to selectively clamp the control cable along the guidewire. Alternatively, a feature of the control cable may be designed to provide an interference fit with the interior of the lumen of the guidewire.

elements

The sheathless filter is preferably comprised of a wire mesh that forms a tubular braided framework over which other members are woven to create the filter surface. In one embodiment, the other fibers are multifilament polymer fibers. In an alternate embodiment, the other fibers are other Nitinol wires of different diameters. The wire used for the framework is biocompatible and has material properties consistent with that needed to create a braided structure. For example, Nitinol wire could be used in this application. In an alternate embodiment, the multifilament polymer fibers that create the filter surface could be woven into a fabric and then attached to the wire mesh.

15 To allow deployment of the sheathless filter on the tubular guidewire, the control cable is longer and has a smaller diameter than the tubular guidewire. Preferably, the outer diameter of the tubular guidewire is 0.018 inches or less. In addition, the proximal end of the guidewire will be free of any mechanical connections and obstructions so as to function as a conventional exchange guidewire.

20 The present invention provides a method of preventing plaque, thrombus or other grumous material and debris from flowing downstream during vascular procedures. The method

includes guiding a tubular guidewire into a blood vessel. A protective filter is then positioned located at the tubular is positioned proximate distal end of the guidewire and distal to the region of the blood vessel to be treated. tubular and affixed to the sheathless filter

A control cable coaxially disposed within the guidewire is displaced, thus expanding the sheathless

protective filter to a deployed state which spans the diameter of the blood vessel. The tubular 5 guidewire is clamped at the proximal end so as to prevent unwanted further displacement of the control cable during the vascular procedure. In a preferred embodiment, the tubular guidewire on outer has a diameter of up to 0.018 inches and is made of Nitinol or comparable material.

A catheter is introduced over the proximal end of the tubular and advanced to the region of the blood vessel to be treated. A vascular procedure is then performed in the area using 10 the catheter. The present invention may be incorporated with a vascular procedure such as an asymmetric water jet atherectomy wherein a jet directs a working fluid at a velocity sufficient to generate a stagnation pressure for removal of ablated deposit debris. The catheter is also proximal exterior primary filter surface used to remove material captured by the convex proximal face of the filter. The control cable is then released from the crimped guidewire thus contracting the filter. The tubular guidewire with 15 sheathless filter is then guided out of the blood vessel.

In the preferred method, the protective filter is comprised of a wire mesh over which other members are co-braided to create a barrier to particles. The wire mesh is attached to the distal end of the control cable and proximate end of the guidewire. The wire mesh and other members are selectively spaced so that particles are captured. In one embodiment, the other 20 fibers are multifilament polymer fibers. In an alternate embodiment, the other fibers are other Nitinol wires of different diameters. Preferably, the fibers and wire mesh are spaced to capture particles of at least 250 microns and more preferably down to 100-150 microns. In the

alternative, the multifilament polymer fibers are woven into a fabric and then attached to the wire ~~mesh~~ ^{braided framework}
~~sheathless~~ ^{braided framework}
~~mesh~~. Before deployment, the ~~Exclusion~~ filter has a closed position in which the wire ~~mesh~~ and
~~or other members~~ ^{and tubular guidewire}
multifilament polymer fibers are disposed generally parallel to the control cable so that the
~~sheathless filter~~ ^{blood}
~~present invention~~ can be inserted into a vessel. ^{or apparatus}

5 The present invention is also a system for filtering emboli from the blood of a patient ^{or apparatus} ^{blood vessel} generally coincident to a vascular procedure. The system includes lumen opening means, debris ^{of a blood vessel} filtering means, and emboli evacuation means. To open the lumen, a catheter ~~with~~ a distal end having one or more orifices from which a working fluid, such as saline under high pressure, is directed in the form of a fluid jet at a deposit within the blood vessel. The jet impacts the deposit
10 longitudinally so as not to damage the blood vessel. The impact dislodges the deposit and creates a plurality of debris particles.

~~blood vessel~~
The lumen opening means further includes a tubular member containing a hypotube. ^{hypotube}
Preferably, the tubular member is used as an evacuation lumen. The ~~lumen~~ further includes one ^{fluid} or more high velocity ^{fluid} jets directed to strike a portion of the tubular member. The high velocity ^{fluid}
15 jet creates ~~a~~ a localized low pressure region which draws the debris particles to the ^{jet} and subsequently down the exhaust lumen.

THE SHEATHLESS

The debris filtering means includes a tube-shaped filter which is advanced distally of the ~~the tubular~~ ^{sheathless} ^{braided} deposit by ~~a~~ guidewire. The tube-shaped filter is comprised of a wire ~~mesh~~ framework over ^{braided} which a plurality of strands are co-braided. The wire ~~mesh~~ framework is radially deployed. The ^{braided wire framework} ^{its} ^{tubular} ^{braided} tube-shaped filter is fixed at ^{its} proximal end to the guidewire and the wire ~~mesh~~ framework is ^{wire} fixed at ^{its} distal end to the control cable. In a non-deployed state, the individual elements of ^{control cable and the tubular} ^{braided} the wire ~~mesh~~ framework lie generally parallel to the guidewire.

sheathless

The ~~Tube-shaped~~ filter can be selectively deployed so as to radially expand to ~~encompass~~

the diameter of the blood vessel. At a lower deployment limit, no fluid is able to pass through ~~sheathless~~ the filter. In a first embodiment, the lower limit for the filter would be 3 mm. Likewise, the ~~Tube-shaped~~ filter has an upper limit based on the unoccupied distance between any two of the

5 strands. This unoccupied distance is defined as a pore size. In a first embodiment, the maximum pore size is 0.010 inch in each direction of the opening so that the ~~Tube-shaped~~ filter would be able to capture particles of 250 microns or greater. Alternatively, the maximum pore size is 0.005 inches so that the filter is able to capture particles of 100-150 microns or greater. In an alternate embodiment, the multifilament fibers are woven into a fabric prior to attaching them to
10 ~~braided~~ the wire ~~mesh~~ framework.

In one embodiment, the debris capturing means includes two filtering surfaces. First, a proximal convex ~~face~~ of the ~~Tube-shaped~~ filter blocks the passage of particles immediately downstream of the vascular procedure. A second debris capturing means includes an interior concave filter ~~face~~ at the distal end of the ~~Tube-shaped~~ filter.

15 The outer diameter of the ~~Tube-shaped~~ filter is smaller than the inner diameter of the blood vessel prior to deployment. In a first embodiment, it is envisioned that the ~~Tube-shaped~~ filter will have an outer diameter of no more than ~~0.046 inches~~ prior to deployment.

In operation, it is envisioned that emboli evacuation would include removing the displaced emboli from the proximal convex ~~face~~ of the ~~Tube-shaped~~ filter through the use of the
20 evacuation lumen. The evacuation lumen is attached to a vacuum pump which provides suction at the distal end. In addition, the evacuation lumen may be driven by the fluid jets which create a stagnation pressure upon striking the mouth of the evacuation lumen. Emboli evacuation is

filter surface *sheathless* further accomplished due to the interior concave *face* at the distal end of the *tube faced* filter *filter surface sheathless* catching emboli that are not trapped by the proximal convex *face*. The filter is contracted and removed from the body upon completion of the procedure. The trapped emboli are maintained *sheathless* within the filter body during the removal procedure.

5 Referring now to FIG. 1-2, the overall *structure and* *or apparatus* operation of a *guidewire filter* protective system *1*

20 in accordance with the present invention will be described. The *guidewire filter* protective *or apparatus*

system 20 *in accordance with one embodiment* includes a guidewire assembly 30, *protective* *tubular* *filter assembly* 50, and a clamp 70. *control cable 38*

10 The guidewire assembly 30 is a tubular member that includes a proximal portion 32 and a distal portion 34. As used in the present invention, the terms proximal and distal will be used with reference to an operator *of the device*, such that *the distal portion* 34 of the guidewire

Assembly 30, for example, is the portion first inserted into a blood vessel, and the proximal *end is the portion which*

portion 32 remains exterior to the patient and is therefore closer to the operator of the device.

15 The guidewire assembly 30 is comprised of a guidewire 36, a control cable 38 and an optional *intermediate shaft* 40. The guidewire 36 is a tubular member having a proximal end 32, which remains exterior to the patient, and a distal end 34 which in operation is proximate a vessel of the patient.

The control cable 38 is a wire having a proximal end 48 and a distal end 49 slidably disposed within the lumen of guidewire 36. The control cable 38 extends proximally and distally beyond the respective ends of the lumen 36. The total length of control cable 38 is longer than

20 *30* *sheathless* guidewire 36 to provide for the filter assembly 50 at the distal end 34 and a gripping region 46 at

gne

the proximal end 32. Exact length for the respective elements is determined by the required path to reach the occlusive site within the patient.

which is attached to the control cable 38

In a preferred embodiment, a flexible guidewire tip 60 is positioned in a sleeve 62 at the distal end 49 of control cable 38 to assist in deployment of the system 20 through the vessel. In 5 one embodiment, a stop ~~rod~~ 66 is crimped on to proximal end 48 of control cable 38 to prevent the control cable 38 from completely sliding into the lumen of guidewire ~~36~~

travel of

a short tube

In one embodiment, the control cable ~~38~~ travel is restricted by an intermediate shaft ~~40~~ disposed within the lumen of guidewire ~~36~~ at the proximal end 32. The intermediate shaft ~~40~~ is a ~~tubular member with~~ ^{has} an inner diameter slightly larger than the diameter of control cable 38 and

tubular 30

10 an outer diameter slightly smaller than the inner diameter of guidewire ~~36~~. The intermediate short tube

~~shaft 40~~ increases the resistive effect on the control cable 38 so as to maintain position relative to guidewire ~~36~~. ^{The} tube ordinarily is in length ~~1~~ ¹ ~~guidewire 36~~. A relatively short intermediate shaft ~~40~~ less than one inch is used to create the resistive effect. The guidewire ~~36~~ is crimpable relative to the intermediate shaft ~~40~~ as it is

~~presumed a clamping tool 70 may also be utilized to maintain position.~~

short tube

15 Alternatively, the intermediate shaft ~~40~~ could be eliminated and position maintained by crimping the proximal end 32 of the guidewire ~~36~~ to the control cable 38, by using a torque

by using a clamp, projection device, by the interaction of a feature on the control cable 38 with the interior diameter of the

guidewire ~~36~~, or simply by maintaining relative position manually. Although the diameter of the

tubular 30

control cable 38 could be of any size consistent with effective use of ~~36~~ guidewire, it will be

20 understood that the larger diameter creates a resistive effect on the guidewire ~~36~~, or intermediate short tube ^{the tubular 30} shaft ~~40~~, so as to maintain position relative to ~~36~~ guidewire ~~36~~ when force is removed.

sheathless

A protective filter assembly 50 having a proximal end 52 and a distal end 54 is located at the distal end 34 of a guidewire assembly 30. The protective filter assembly 50 is preferably comprised of a wire mesh framework 56 over which a plurality of multifilament polymer fibers to form a filter mesh 58 are braided. Alternatively, the wire mesh framework 56 may support a mesh of other fibers or wires, such as a Nitinol mesh of wires, as shown in FIG. 11. The proximal end 52 of the sheathless filter assembly 50 is laser-welded to the distal end 34 of guidewire 30 as shown in FIG. 12, for example, while the distal end 54 of the sheathless filter assembly 50 is laser-welded to the distal end 49 of control cable 38. In one embodiment, a control cable stop 68 is disposed on control cable 38, between the proximal end 52 and distal end 54 of filter assembly 50, so as to limit the travel of control cable 38. Exact location of the stop 68 is determined by the filter spacing created upon radial expansion of the wire mesh framework 56 as compared to the particle size to be filtered.

The individual wire elements 64 of wire mesh framework 56 are disposed parallel to guidewire 30 and control cable 38 at the point of attachment so as to present a minimal crossing profile. Individual monofilament polymer fibers 58 are co-braided about the wire mesh 56 to increase cross-section coverage without the stiffness associated with the wires 64. Alternatively, the members 58 may be comprised of smaller diameter wires that exhibit more flexibility than the wires 64 associated with the framework 56. In one embodiment, the filter assembly 50 may be coated with a hemocompatible compound to minimize shear activation of platelets.

During interventional procedures involving carotid arteries and saphenous vein bypass grafts, embolic particles may be liberated causing adverse complications if preventive means are not in place. In a preferred embodiment, as illustrated in FIGs. 1-6, the guidewire filter

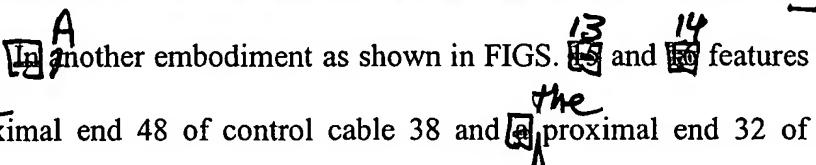
~~protective or gripping~~ ³⁰
 Eclusion system ²⁰ provides embolic protection. In one embodiment, the tubular guidewire ~~5~~ ¹ is formed of a ~~Nitinol~~ ³⁰ ~~tube~~ having an outer diameter of 0.014 inches, an inner diameter of 0.010 inches, and a length of 180 cm. In an alternate embodiment as shown in FIG. 8-10, the tubular guidewire ~~30~~ ³⁰ is formed of a braided polyimide tube having an outer diameter of 0.015 inches, an inner diameter of 0.011 inches, and a length of 180 cm, such as available from MedSource Technologies, Trenton, Georgia. In one embodiment, the control cable ³⁸ is formed of a ~~Nitinol~~ ^{wire} ~~rod~~ having a diameter of 0.008 inches and a length of 190 cm. In an alternate embodiment, the control cable 38 is formed of a Teflon® coated stainless steel ~~rod~~ ^{wire} having a diameter of 0.095 inches. The control cable ~~38~~ ³⁰ is disposed coaxially with the guidewire ~~30~~. Although the length of the guidewire ~~30~~ ³⁰ could be any length, it will be understood that it will be shorter than the length of control cable 38. In a first embodiment, the control cable 38 will be at a minimum of 10 cm longer so as to provide for the attachment of the filter ~~assembly~~ ⁵⁰ at the distal ^{end} ~~portion~~ ^{region} ³⁴ and a gripping ~~area~~ ^{end} ³⁴ at the proximal ^{end} ³². In one embodiment, ~~intermediate shaft~~ ⁴⁰, is also preferably made of ~~Nitinol~~ with a length of 0.05 inches. ^{short tube} ^{49 of the control cable 38}
 As shown in FIG. 1, the guidewire tip 60 is disposed at the distal end ³⁴ of the guidewire ^{assembly} ³⁰. The guidewire tip 60 is preferably a platinum coil with a stainless steel core having a maximum diameter of 0.018 inches and a length of 1.0 inch. Attachment of guidewire tip 60 is accomplished in one embodiment by a stainless steel sleeve 62 that is laser-welded to control cable ~~core~~ ³⁸. A crimp is applied to the sleeve 62 to hold the tip 60 in place. FIG. 10 shows an alternate embodiment ^{60a} ^{wherein} ^{thereof} of the construction of the guidewire tip 60 where the core is fabricated ⁶³ ⁶¹ ^{flexible} ^{cable 38} as part of the control ^{flexible} ^{guidewire} ^{60a} ^{core} ⁶² ^{thereof}.

In one embodiment, at the proximal end 48 of control cable 38, a ~~cable~~ stop ~~rod~~ 68 is attached. In this embodiment, ~~cable~~ stop ~~rod~~ 68 is 0.25 inches long with a diameter of 0.014 inches, which is equal to the diameter of guidewire 30. The ~~cable~~ stop ~~rod~~ 68 is crimped on to control cable 38 and serves to keep the proximal end 48 of the control cable 38 from entering into the tubular guidewire 30

5 ~~In an alternate embodiment as shown in FIGS. 13 and 14, a hemostatis like clamp arrangement 80 is utilized on the proximal end 48 of guidewire assembly 20 to secure the control cable 38 relative to the tubular guidewire 30. The clamp arrangement 80 preferably consists of an actuator assembly 82 that is secured to the tubular guidewire 30 and an indicator assembly 84 that clamps onto the control cable 38 by rotation of a knob member 86 that pinches control cable~~

10 ~~38 in a wedge structure 88. In one embodiment, the distal end of actuator assembly 82 is provided with structure 90 that attaches the actuator assembly 82 to the guidewire by a torque device, such as a collet clamp. Preferably, both the actuator assembly 82 and the indicator assembly 84 have mated threads 92 that permit the actuator assembly 82 to threadably receive the indicator assembly 84. The indicator assembly 84 preferably includes visible markings at 94 that indicate to an operator the extent of the deployed state of the filter device 50 based on the number of turns of knob 86 as the indicator assembly 84 is unscrewed and control cable 38 is displaced relative to the tubular guidewire 30. It will be understood that alternative arrangements for securing the control cable 38 and tubular guidewire 30 can be used with the indicator assembly such as a pin vise or bearing arrangement, and that a latch, ratchet or other step-wise mechanical interface could be utilized in place of the threads 82.~~

15 ~~20~~



A
In another embodiment as shown in FIGS. 13 and 14 features an interference fit between the proximal end 48 of control cable 38 and the proximal end 32 of tubular guidewire 30 that

sheathless
effectively locks the ~~protective filter assembly~~ 50 into a minimum diameter or undeployed state

10 during insertion ~~of the guidewire assembly~~. This feature is particularly useful to *e* insure that the ~~sheathless~~
~~filter assembly~~ 50 remains in as unobtrusive a state as possible during passage ~~of the distal tip 34~~
~~of the guidewire~~ through lesions or tortuous areas of the vessel undergoing a vascular procedure.

15 *The fit is created by a projection which*
5 ~~interference feature~~ 96 on the control cable 38 frictionally interfaces with the proximal opening of the lumen of the tubular guidewire 30 to secure the relative position between the two.
projection
In this embodiment, the ~~interference feature~~ 96 is a frustoconical-shaped member that extends beyond the outer diameter of the control cable 38. Numerous other shapes and configurations such as a lipped configuration or a ratchet arrangement could also be used.

20 *sheathless filter* *wire elements* *braided wire*
10 ~~Filter assembly~~ 50 is comprised of a plurality of ~~filter wires~~ 64, which form a framework *fibers or* *formed into a filter mesh*
56 to support a plurality of polymer strands 58 as illustrated in FIG. 6. In a first embodiment, the *fibers or* *braided*
polymer strands 58 are co-braided around the ~~wire mesh~~ framework 56. The ~~wires~~ 64 are made of Nitinol, a super-elastic nickel titanium alloy, which is the preferred material because it is easy to braid and biocompatible. A plurality of laser-welds are applied at the ~~distal filter end~~ 52 and *proximal*

15 *distal* *the wire elements*
15 ~~proximal filter end~~ 54 to hold the ends of ~~filter wire~~ 64 in position and prevent fraying. At least *element* *each element*
two welds are performed on each ~~wire~~ 64 at each end so as to hold ~~the wire~~ 64 as small as possible, thus presenting a minimal profile *in that deployment without a sheath*. Alternatively,

adhesive bonds or mechanical interconnections may be used in place of or in addition to welding *sheathless*

20 *sheathless*
to secure the ~~filter assembly~~ 50. In an alternate embodiment as shown in FIGS. 11 and 12, the *forming the filter mesh*
strands 58 are also comprised of Nitinol wire having a smaller diameter (e.g., 0.008") than the *INCH*
Nitinol wire elements *Wire 64 (e.g., 0.012")* *INCH*

It is expected that the radial expansion of the filter ~~assembly~~ 50 will have an upper and lower limit based on blood flow requirements at the lower limit and the ability to stop particles of an expected size at the upper limit. In a first embodiment, the lower limit of expansion would provide filtration in vessels as narrow as 3 mm. In order to filter particles of 250 microns or 5 larger, the maximum allowable mesh gap would be 0.01 inches which corresponds to a maximum deployment diameter of 0.3 inches. In the closed position, as depicted in FIG. 3, the maximum diameter of the non-deployed filter 50 is 0.038 inches.

In another embodiment as shown in FIGS. 8-12, the filter ~~assembly~~ is designed to filter particles down to a size of between 100-150 microns. The inter-mesh spacings required for such 10 a filtration effect range between 0.004 inches and 0.008 inches as can be seen in FIG. 11, for example. In this embodiment, the expansion size of the filter ~~assembly~~ 50 in a deployed state is selected among a plurality of sizes (e.g., 2-4 mm diameter vessels, 4-6 mm diameter vessels, 6-8 mm diameter vessels) to control the filtration effect of a given sized filter by providing a known range of diameters in the deployed state for which the inter-mesh spacings necessary to achieve 15 the desired filtration effect can then be chosen. In tests with the filter ~~assembly~~ of the present invention deployed within a 6.2 mm acrylic tube, polymer particles of ~~known~~ size were introduced into a fluid flow simulating blood to determine the effectiveness of the filter ~~50~~ ^{sheathless 50} ~~assembly~~. When particles of a size of 200 microns were used in this test, 100% of the particles ^{primary surface} ~~sheathless 50~~ were trapped by the ~~first~~ convex filter of the filter ~~assembly~~. When the particle size was reduced 20 to 157 microns, 50% of the particles were trapped by the ~~first~~ convex filter, 40% were trapped by the ~~second~~ concave filter and approximately 10% of the particles flowed through the ~~protective device~~. It will be seen that the sizes of the inter-spacing pores may be adjusted if protection for

smaller size particles is desired to improve the effectiveness of the ~~protective device~~ for particles at those smaller sizes while potentially reducing the flow of blood due to the use of the smaller size pores.

sheathless

(see FIGS. 4 and 5)

To limit radial expansion of filter ~~assembly~~ 50, in one embodiment ~~control cable stop~~ 68 ~~52 and 54~~ ~~sheathless~~ 5

is coaxially disposed on control cable 38 between the proximal and distal ends of filter ~~assembly~~

50. ~~Cable~~ ⁵ stop 68 is a stainless steel tube crimped on to control cable 38 with an outer diameter of 0.012 inches which stops the control cable 38 from traveling into the lumen of guidewire ~~50~~.

~~fibers, strands or~~ ^{of the filter mesh} ~~the wire elements 64 of the braided wire framework 56~~
 The wires ⁵⁸ and strands ⁶⁰ lie generally parallel to control cable ~~core~~ 38 when inserted ⁵⁴
~~into~~ ⁵⁴ ~~blood~~ ⁵² a vessel. As control cable ~~core~~ 38 is proximally extended, distal ~~filter~~ end ⁵² is drawn toward

10 stationary proximal ~~filter~~ end ⁵⁴. Initial displacement, as depicted in FIG. 4, for example, ^{sheathless 50} ~~expands~~ creates a narrow tube as the filter ~~wires expand~~ ^{sheathless} radially in an elastic manner to form a thin tube.

As the control cable ~~core~~ 38 is further displaced, the filter ~~wires 58 continue their radial~~ ^{sheathless 50}
~~continues its radial~~ ^{68 reaches distal end 34 of blood} ~~expansion, as depicted in FIG. 5, until~~ ^{takes place} ~~reaching stop 62 or filling the vessel~~

15 It will be understood that the weave of filter ~~assembly~~ 50 may be varied in a number of ^{changing} ^{the multifilament} ^{changing} ways including: ^{changing} ~~the number of filaments per strand of polymer fiber~~ ^{changing} ^{the} ^{changing} ^{in wire elements} ^{braided} ^{framework 56 changing the wires and/or wire elements changing} ^{mesh skeleton} ^{changing} ^{the diameter of Nitinol strands} ^{changing} ^{the design of the tubular}

weave. A further advantage to this design is the "softness" created by the polymer fibers as they

20 ^{in wire elements} ^{number of wire elements} interact with the blood vessel. Varying the ~~Nitinol strands~~ has a direct effect on the stiffness of ^{sheathless 50} ^{number of wire elements} the filter and the "softness." However, the ~~Nitinol strand number~~ must be sufficient to adequately constrain the multifilament polymer fibers. Clearly, the options described above may

strengthless 50

be used to tighten or relax the weave of the filter. Furthermore, the options may be combined to achieve comparable results.

In practice, medical personnel gain access to the blood vessel lumen through which the *protective system or apparatus* *or apparatus* *guidewire assembly 20* will travel. The *guidewire filter* protective system 20 is removed from *flexible guidewire* *blood vessel* 5 biocompatible packaging. *Guidewire tip 60* is inserted into the lumen and is manipulated to a point beyond the vessel occlusion. The control cable 38 is drawn *distally* from the tubular *guidewire* *strengthless blood vessel* 30 *so as to radially deploy the filter 50 within the lumen. A rapid exchange device, such as a stent catheter or thrombectomy device, is then deployed on the tubular guidewire* *strengthless* *30* *with the filter assembly 50 in a deployed state. As illustrated in FIG. 7, a clamp 70 is then applied to the guidewire assembly 20* *control cable 38* *strengthless* *30* *to maintain the deployed position of the filter 50 until completion of the procedure.*

In a preferred embodiment of the present invention, the *guidewire* protective system 20 is utilized *as the guidewire for* *an atherectomy or thrombectomy procedure of the type described in U.S. Patents Nos. 5,370,609 or 5,496,267, the disclosure of each of which is hereby incorporated by reference. In each of these embodiments, the* *guidewire* protective system 20 is *strengthless* introduced into the patient, the filter 50 is radially deployed, and then the atherectomy or *tubular* *thrombectomy catheter arrangement is slid over the proximal end 32 of the guidewire assembly* *strengthless* *30 and advanced until it is proximate and proximal to the location of the filter assembly 50.* Unlike other occlusive methods, the time period of the procedure is not constrained by concern *blood* *strengthless* *over blockage of the vessel. The radial expansion of filter assembly 50 allows for the continual strands of the filter mesh* *strengthless* *flow of blood through the spacing between individual polymer fibers 58. Thus, filter assembly* *strengthless*

50 is preferable where ischemia is intolerable or further blood cessation would be irreparably damaging.

Preferably, an evacuation of any debris ~~or other plaque material~~ dislodged in the therapy is accomplished by the evacuation lumen incorporated within the catheter assembly of the above-
5 referenced patents. However, should debris ~~or plaque~~ escape the evacuation lumen, the convex ^{proximal exterior}
~~filter surface~~ ^{sheathless} ~~sheathless~~ ^{filtering surface}
~~proximal face~~ ^{filter surface} ~~sheathless~~ ^{secondary}
~~distal interior~~ ^{filter surface} ~~sheathless~~ ^{sheathless 50}
The concave ~~interior face~~ ^{filter surface} ~~sheathless~~ ^{filter assembly} 50 provides a ~~second~~ filtering surface.
Additionally, a sponge could be compressed to fit within the collapsed ~~filter assembly~~. Upon
deployment, the sponge would provide a third level of filtering. After completion of the
10 procedure, the filter ~~assembly~~ is returned to an undeployed state and the guidewire ^{tubular} ⁵⁰ ~~assembly~~
~~sheathless~~ and filter ~~assembly~~ 50 are retracted.

The present invention may be embodied in other specific forms without departing from the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather
15 than to the foregoing description to indicate the scope of the invention.

ABSTRACT OF THE DISCLOSURE
protective or apparatus

a tubular guidewire, a control cable slideable within the tubular guidewire, and

A ~~guidewire protection~~ system for use in vascular procedures includes a sheathless

~~protective filter proximate a distal end of a tubular guidewire assembly. In one embodiment, a~~

~~control cable disposed within the guidewire~~ is attached to a distal end of the filter ~~while the~~
~~tubular~~ ~~sheathless~~ and

5 ~~A guidewire is attached to a proximal end of the filter. Selective displacement of the control cable~~

~~sheathless~~ ~~proximal exterior~~

~~radially expands the filter to create a tube-shaped filter having a convex primary filter surface~~

that is positionable downstream from a site of a vascular procedure. ~~In this embodiment, the~~

~~the sheathless distal interior~~

~~A filter also presents a concave secondary filter surface. Preferably, the sheathless protective filter~~

~~framework in the form of a tube woven or strands applied a filter mesh having~~
~~is constructed of a braided wire mesh over which polymer fibers are woven to create a softer~~

10 filter surface.